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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/550,985 | 09/26/2005 | Daria Onichtchouk | 18744-0033 | 4668 |
| 29052 7590 12/29/2006 SUTHERLAND ASBILL & BRENNAN LLP 999 PEACHTREE STREET, N.E. ATLANTA, GA 30309 | | | EXAMINER SGAGIAS, MAGDALENE K | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1632 | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 31 DAYS | | 12/29/2006 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/550,985

Applicant(s)

ONICHTCHOUK ET AL.

Examiner

Magdalene K. Sgagias

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2005.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 37-63 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 37-63 are pending. Claims 1-36, 64-82 are canceled.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) **37-45**, drawn to a method for treatment using as a pharmaceutical composition a saposin-related product and/or modulator/effector thereof to promote the protection, survival and/or regeneration of insulin producing cells comprising administering to the cells of a patient in need thereof an effective amount of a saposin-related product and/or a modulator/effector thereof.

Group II, claim(s) **37-43, 51**, drawn to a method for treatment using via implantation of saposin-related protein product expressing cells, a saposin-related product and/or modulator/effector thereof to promote the protection, survival and/or regeneration of insulin producing cells comprising administering to the cells of a patient in need thereof an effective amount of a saposin-related product and/or a modulator/effector thereof.

Group III, claim(s) **37-43, 46**, drawn to a method of treatment using via gene therapy a saposin-related product and/or modulator/effector thereof to promote the protection, survival and/or regeneration of insulin producing cells comprising administering to the cells of a patient in need thereof an effective amount of a saposin-related product and/or a modulator/effector thereof.

Group IV, claim(s) **47-49, 52-61**, drawn to a method of using a saposin-related product to differentiate cells, wherein the differentiation of progenitor, e.g. stem cells into insulin-producing cells in vitro comprises a) optionally activating one or more pancreatic gene sin progenitor cells, b) optionally aggregating said cells to form embryoid bodies, c) cultivating said cells or embryoid bodies in specific differentiation media containing saposin-related protein product, and d) identifying and optionally selecting insulin-producing cells, wherein method for differentiating or regenerating cells into functional pancreatic cells, the method comprising: (a) cultivating cell capable of being differentiated or regenerated into pancreatic cells in the presence of an effective amount of a saponin-related protein in vitro; (b) allowing the cells to develop, to differentiate and/or to regenerate at least one pancreatic function; and (c) optionally preparing

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an effective amount of the differentiated or regenerated pancreatic cells for transplantation into a patient in need thereof, particularly a human individual..

Group V, claim(s) **47-49**, drawn to a method of using a modulator or effector of saposin-related-product to differentiate cells, wherein the differentiation of progenitor, e.g. stem cells into insulin-producing cells in vitro comprises a) optionally activating one or more pancreatic gene sin progenitor cells, b) optionally aggregating said cells to form embryoid bodies, c) cultivating said cells or embryoid bodies in specific differentiation media containing saposin-related protein product, and d) identifying and optionally selecting insulin-producing cells, wherein the saposin-related treated insulin producing cells are (i) capable of a response to glucose and/or (ii) capable of expressing glucagon in vitro.

Group VI, claim(s) **61-63**, drawn to a method of using cells expressing a saposin-related protein for differentiating or regenerating cells into functional pancreatic cells, the method comprising: preparing an effective amount of cells capable of expressing a saposin-related protein product for administration to a patient in need thereof.

Group VII, claim(s) **50**, drawn to a method for treatment by implanting with in vitro saposin-related cells, wherein the in vitro saposin-related cells are natural producers of saposin-related protein, wherein an effective amount of in vitro saponin-related cells are transplanted to a patient in need thereof.

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single inventive concept. Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. See 37 C.F.R 1.475 (a). If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and first recited invention of each of the other categories related thereto will be considered as the main invention in the claims. See 37 C.F.R

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1.475 (d) and 37 C.F.R 1.476 (c). For example, the inventions of group I does not require the treatment using via implantation of saposin-related protein product expressing cells, a saposin-related product and/or modulator/effector thereof to promote the protection, survival and/or regeneration of insulin producing cells comprising administering to the cells of a patient in need thereof an effective amount of a saposin-related product and/or a modulator/effector thereof of group II. Accordingly, Groups I-VII are not linked by a special technical feature.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Magdalene K. Sgagias whose telephone number is (571) 272-3305. The examiner can normally be reached on Monday through Friday from 9:00 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, Jr., can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Magdalene K. Sgagias, Ph.D.
Art Unit 1632



DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800/1630